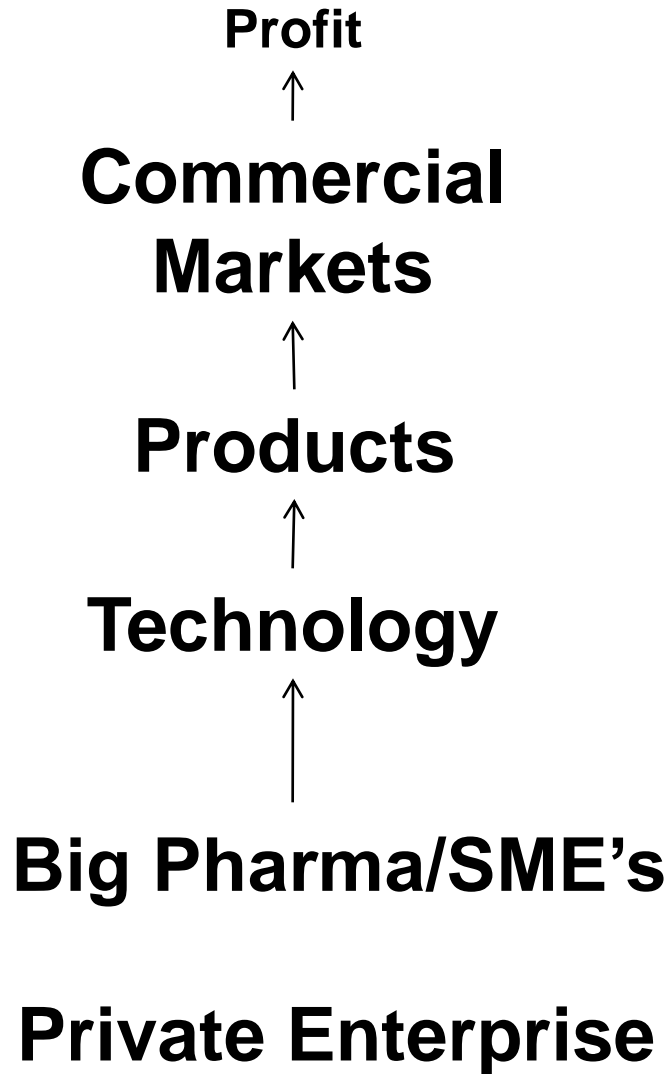


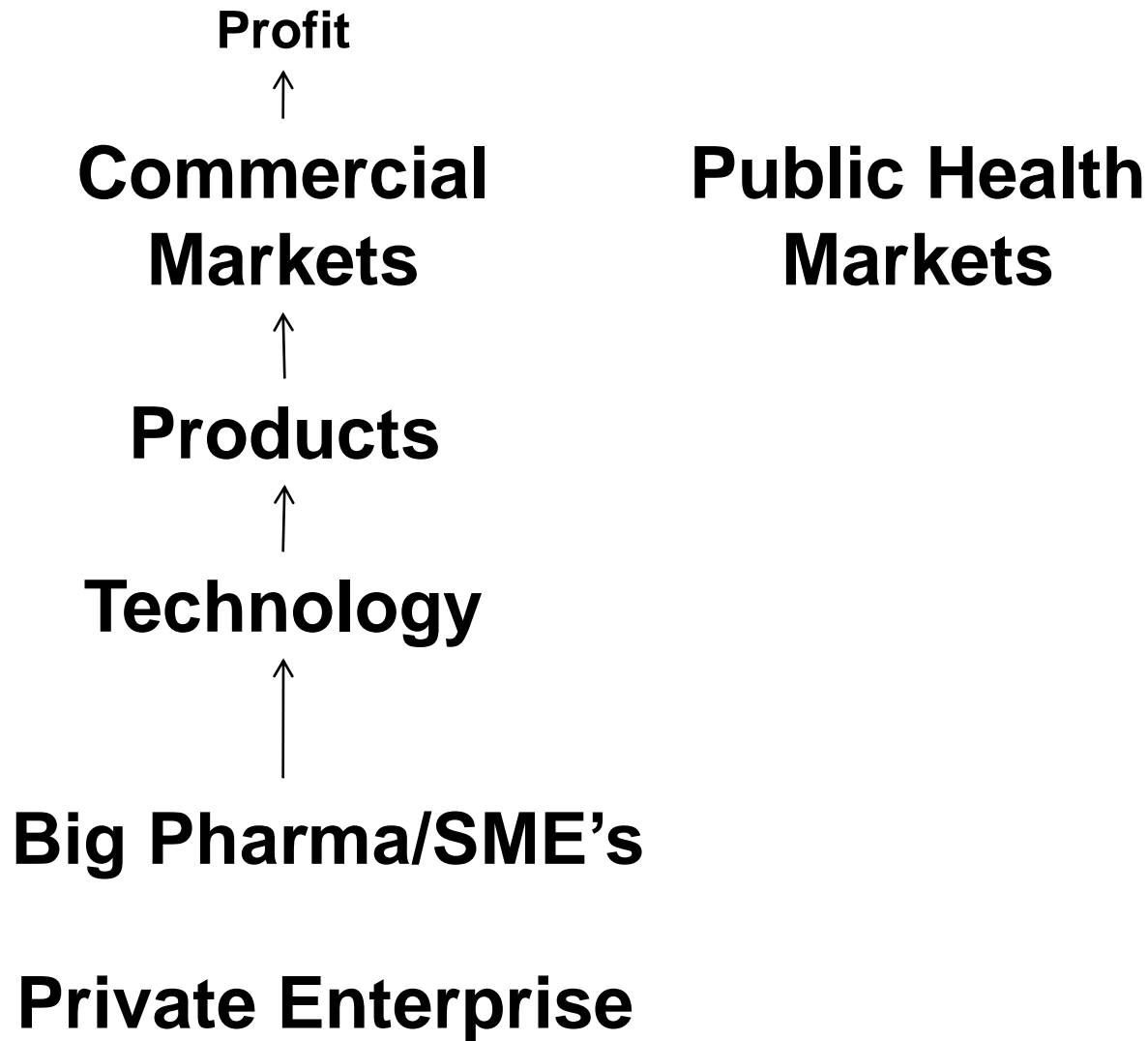


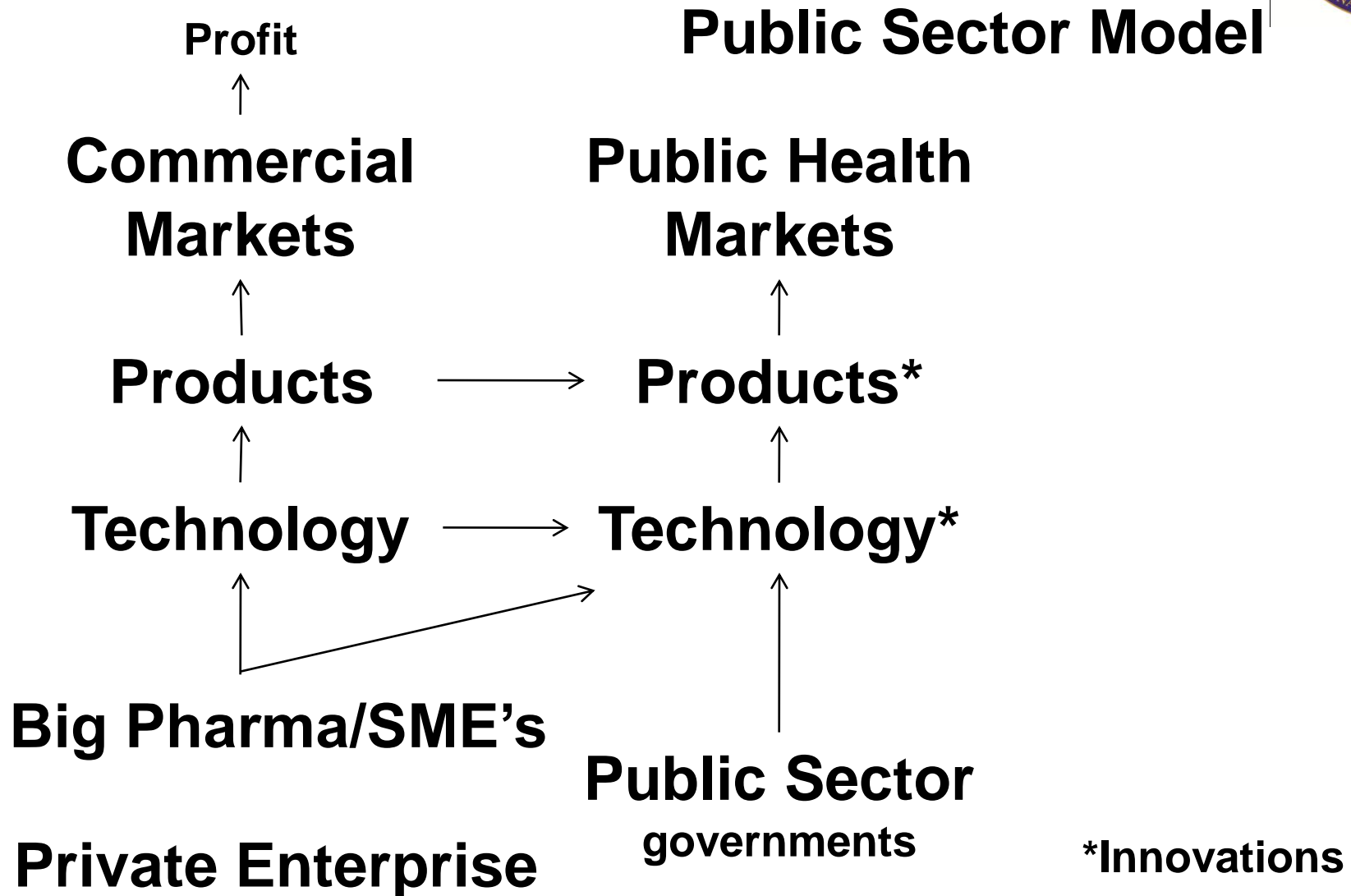
International Vaccine Technology Workshop

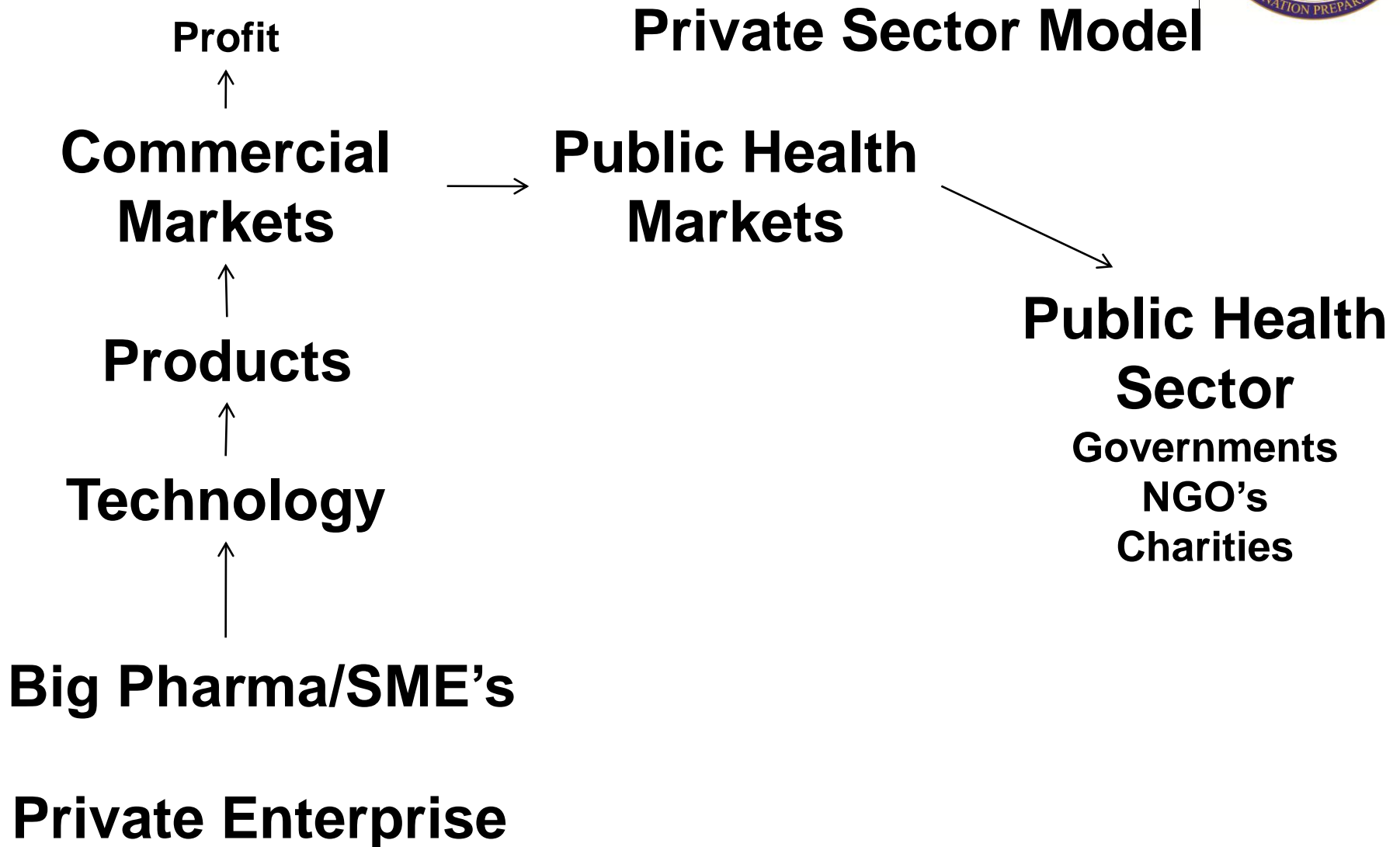
Research Needed for New Technologies

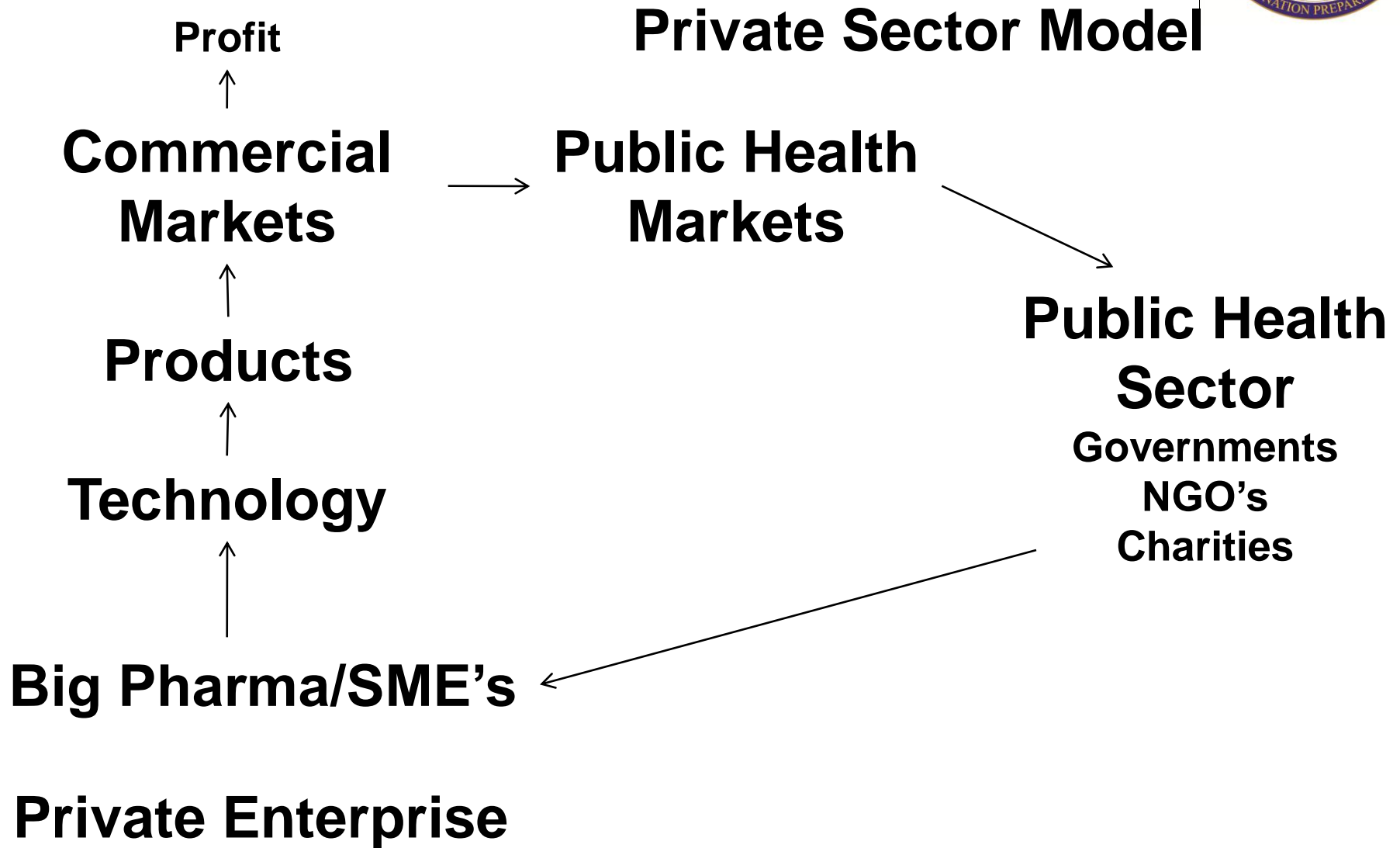
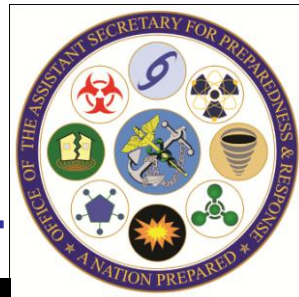
Jonathan Seals
Director, Strategic Science and Technology
HHS/ASPR/BARDA

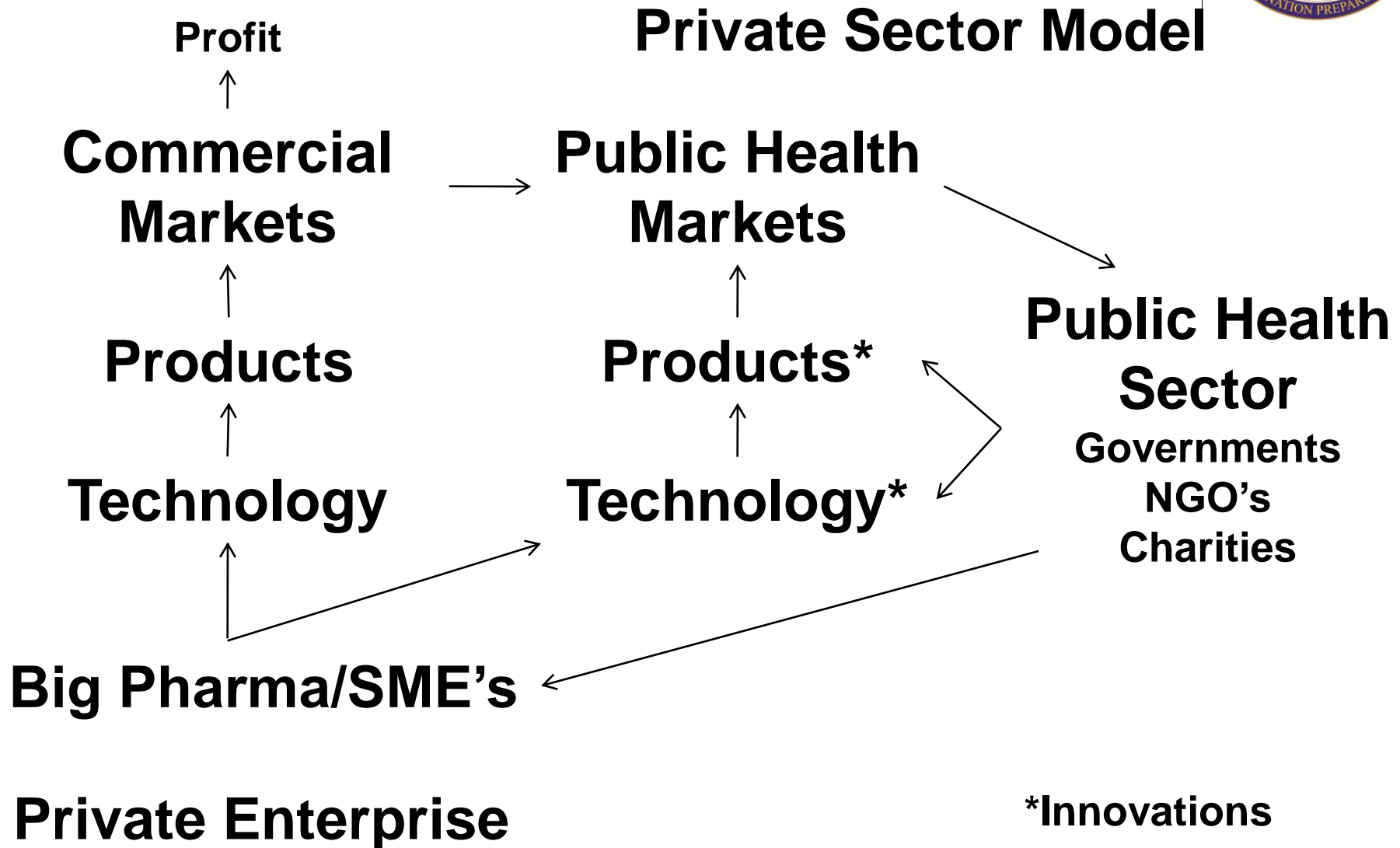
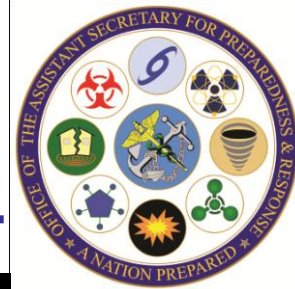


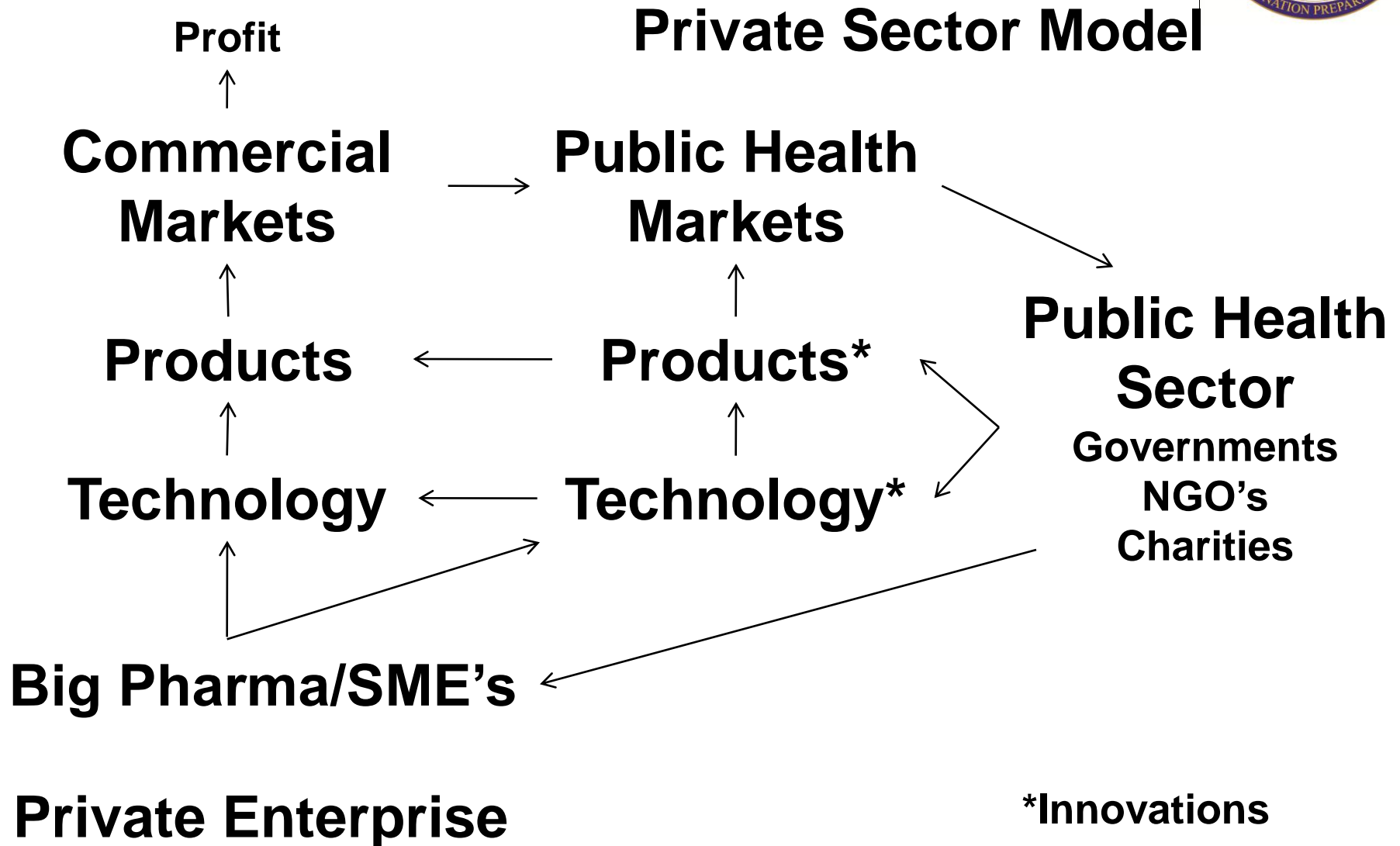
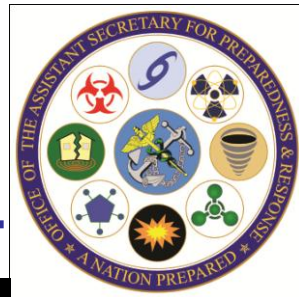


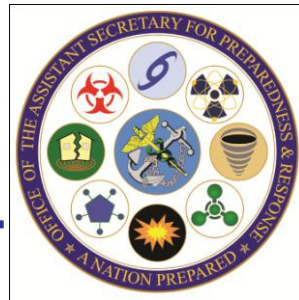






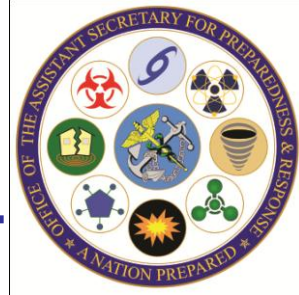






Public Health Sector support drives

- **Production of vaccines for which there is not a profitable market**
- **Construction and maintenance of manufacturing capacity beyond what is needed for commercial use**
- **Development and licensure of vaccines for which there are not profitable markets**
- **Development and evaluation of innovative technologies and products that have a higher risk profile than established technologies**
- **Comparison of innovative and established technologies and licensure of advantageous new products and processes**



Technologies for Vaccine Production

Established

- **Killed or live vaccines**
- **Egg or cell production**
- **One-by-one development**
- **Dedicated facilities**
- **Reusable stainless steel**
- **Fixed capacity**
- **Capital-intensive**
- **High incremental cost**
- **Regulatory clarity**
- **Low-risk**

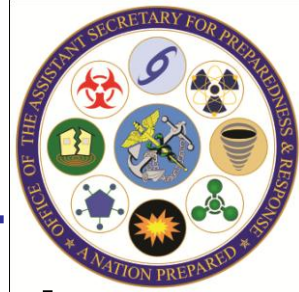
Evolving

- **Engineered vaccines**
- **Alternate production hosts**
- **Platform technologies**
- **Flexible facilities**
- **Disposable technology**
- **Surge capacity**
- **Capital-sparing**
- **Low incremental cost**
- **Regulatory uncertainty**
- **High-risk**



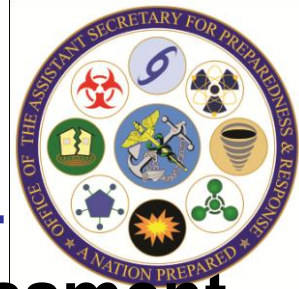
Technologies for Building Vaccine Capacity

- **Established**
 - Record of success and reliability
 - Regulatory history
 - Capital-intensive
 - Capacity, cost limitations
- **Evolving**
 - Unproven performance
 - Uncertain path forward
 - Possible simpler infrastructure
 - Potential for higher capacity, lower cost



Research Gaps in Evaluation of Technical Options

- **Full development of innovative products and technology**
- **Comparison of innovative products and technologies with established systems**
- **Late-stage support for small biotechs**
 - Development capability and expertise
 - Production capacity
- **Regulatory clarity**
- **Clinical trial capacity**



Funding Opportunities for Technology Assessment

- **U.S. government**
 - HHS (ASPR/BARDA, OGHA, NIH, CDC, FDA)
 - DOD
- **WHO**
- **PATH**
- **Other American, European, and Asian governments**
- **Other NGO's and charities**
- **PDP's**
- **Industry**
 - Commercial operations
 - Research institutes



Path Forward

- **Public Health sector needs to be proactive in supporting and directing vaccine development and manufacturing in ways that best achieve its goals**
- **Public Health sector funders need to evaluate best solutions to meeting vaccine availability needs**
- **Growing markets in the developing world will attract increased interest from private enterprise in supplying vaccine**
- **Partnership models that involve governments, public health advocates, and industry are likely to prove the most effective path to finding solutions for vaccine availability**